Claims :

1. (Previously Amended) A method of monitoring the compliance of a patient in following a medication regimen, said method comprising the steps of:

providing in combination an orally administrable composition, which is part of a medication regimen, and at least one marker, said at least one marker being present in said combination in a form and sufficient amount to cause a contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity of a patient following oral ingestion of said combination by said patient;

visually observing the oral and/or pharyngeal cavity of said patient; and

determining the presence or absence of said contact coloration for determining whether said patient has ingested said combination in compliance with the medication regimen.

2. (Original) The method of claim 1 wherein said composition is a medication composition.

3. (Original) The method of claim 1 wherein said composition is a placebo composition.

4. (Previously Amended) The method of claim 1 wherein visually observing the oral and/or pharyngeal cavity of said patient to determine the presence or absence of contact coloration further comprises the step of directing natural light into the oral and/or pharyngeal cavity of said patient prior to observing the oral and/or pharyngeal cavity of said patient in order to directly observe said contact coloration.

5. (Previously Amended) The method of claim 1 wherein visually observing the oral and/or pharyngeal cavity of said patient to determine the presence or absence of contact coloration further comprises the step of directing an optimal exciting light into the oral and/or pharyngeal cavity of said patient prior to observing the oral and/or pharyngeal cavity of said patient in order to observe said contact coloration through fluorescence.

6. (Original) The method of claim 5 wherein said optimal exciting light is a violet-blue to blue light having a wavelength in a range of from about 430 nm to about 490 nm.

7. (Original) The method of claim 1 wherein visually observing said oral and/or pharyngeal cavity comprises visually observing a mucous membrane in said oral and/or pharyngeal cavity.

8. (Original) The method of claim 1 wherein said marker is carmine red dye.

9. (Original) The method of claim 1 wherein said marker is selected from the group consisting of indigo carmine, methylene blue, tartrazine, laccaic acid, beta-carotene, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 6, and riboflavin.

10. (Previously Amended) The method of claim 1 further comprising providing multiple markers in said combination, one of said markers causing a contact coloration of portion of the oral and/or pharyngeal cavity for a longer time than another of the markers, and determining the presence or absence of contact colorations caused by the multiple markers to determine a time frame in which the combination was ingested.

11. (Previously Amended) The method of claim 10 wherein one of said multiple markers causes a different contact coloration in the portion of the oral and/or pharyngeal cavity than another of said markers.

12. (Previously Amended) The method of claim 1 further comprising providing multiple markers in said combination wherein one of said multiple markers causes a different contact coloration in the portion of the oral and/or pharyngeal cavity than another of said markers.

13. (Previously Amended) The method of claim 1 further comprising providing multiple markers in said combination, one of said markers causing a contact coloration of a portion of the oral and/or pharyngeal cavity detectable with natural light and another of said markers causing contact coloration detectable with a light which causes fluorescence.

14. (Previously Amended) The method of claim 1 further comprising providing multiple markers in said combination, the markers being detectable with a light which causes fluorescence, one of said markers causing a different fluorescent contact coloration of a portion of the oral and/or pharyngeal cavity than the fluorescent contact coloration caused by the other marker.

15. (Currently Amended) In combination:

an orally administrable composition; and

at least one marker, said marker being present in said combination in a sufficient amount and form to cause a contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity of a patient following ingestion of said combination by said ~~subject~~ patient;

said contact coloration of the oral and/or pharyngeal cavity being visually observable for determining whether said patient has ingested said combination in compliance with a medication regimen.

16. (Original) The combination of claim 15 wherein said at least one marker is applied to the outer surface of said composition.

17. (Original) The combination of claim 15 wherein said at least one marker is interspersed throughout said composition.

18. (Original) The combination of claim 15 wherein the form of said composition is selected from the group consisting of a chewable tablet, a pill, a capsule, and a liquid.

19. (Previously Amended) The combination of claim 15 wherein said marker is operable to cause contact coloration of a mucous membrane of said oral and/or pharyngeal cavity.

20. (Original) The combination of claim 15 wherein the half-life of said at least one marker in the human system is comparable to the half-life of said composition in the human system.

21. (Original) The combination of claim 15 wherein said at least one marker is carmine red dye.

22. (Original) The combination of claim 15 wherein said at least one marker is selected from the group consisting of indigo carmine, methylene blue, tartrazine, laccaic acid, beta-carotene, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 6, and riboflavin.

23. (Original) The combination of claim 15 further comprising multiple markers in said combination.

24. (Previously Amended) The combination of claim 23 wherein one of said multiple markers causes a contact coloration of portion of the oral and/or pharyngeal cavity for a longer time than another of the markers so that the presence or absence of contact colorations caused by the multiple markers may be visually observed to determine a time frame in which the combination was ingested.

25. (Previously Amended) The combination of claim 23 wherein one of said multiple markers causes a different contact coloration in the portion of the oral and/or pharyngeal cavity than another of said markers.

26. (Previously Amended) The combination of claim 23 wherein one of said multiple markers causes a contact coloration of a portion of the oral and/or pharyngeal cavity

detectable with natural light and another of said markers causes contact coloration detectable with a light which causes fluorescence.

27. (Previously Amended) The combination of claim 23 wherein the multiple markers are detectable with a light which causes fluorescence, one of said markers causing a different fluorescent contact coloration of a portion of the oral and/or pharyngeal cavity than the fluorescent contact coloration caused by the other marker.

28. (New) The method of claim 1, wherein said combination is in a form and sufficient amount to cause a contact coloration directly on at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity.

29. (New) In combination:

an orally administrable composition; and

at least one marker, said marker being present in said combination in a sufficient amount and form to cause a contact coloration directly on at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity of a patient following ingestion of said combination by said patient;

said contact coloration directly on the oral and/or pharyngeal cavity being visually observable for determining whether said patient has ingested said combination in compliance with a medication regimen.